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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,600	11/14/2000	Victor T. Chen	044407:0684	3680

7590

09/24/2003

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/712,600

Applicant(s)

CHEN ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4/14/03 & 6/20/03 (Responses & RCE).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-31,33-59 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) 22-29,53-59 and 63-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-21,30,31,33-52 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 4/14/03 has been entered.

***Election/Restriction***

2. Claims 22-29, 53-59 and 63-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No.14.

In response to the restriction requirement, the Applicant asserts claim 1 is a linking claim that links the claims in the Groups I.-VI.. The Examiner disagrees. Independent claims 22, 53 and 63 of Groups III.-V. include the limitation of providing an algorithm that provides an indication of the type of tachycardia identified, a limitation not found in claim 1. Independent claims 22 and 63 of Groups III. and V. provide no pacing therapy as found in claim 1. Independent claim 64 of Group VI. includes the limitation of providing an atrial discrimination therapy output, a limitation not found in claim 1.

The Applicant elected without traverse to prosecute Group I. Upon reconsideration, it appears Group I. and II. comprise a single invention, hence Groups I. and II., claims 1, 3-21, 30, 31, 33-52 and 62 are being prosecuted.

***Claim Rejections - 35 USC § 102***

3. Claims 1, 3, 5-14, 16-21, 30, 31, 33, 35-45, 47-52 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Gillberg et al. (US 5755736). Gillberg et al. disclose an implantable anti-tachyarrhythmia device that delivers therapies in response to detected tachyarrhythmias. A prioritized set of inter-related rules and clauses (criteria) detect arrhythmias using multi-dimensional threshold comparisons relative to a plurality of statistical measurements (col. 2 @ 14-39). Also event classification occurs based on analysis of a sequence of two depolarizations (col. 2 @ 48-53; col. 17 @ 15-27), read as a morphology based system. Atrial (15) and ventricular (16) leads are provided. The pacer/timing control circuitry is used to employ any pacing therapy known in the art (col. 6 @ 36-39), read to include ventricular pacing, ventricular rate regulation, ventricular rate smoothing and dual chamber brachycardia pacing. Tachyarrhythmias detection algorithms known in prior art may be included in this invention (col. 7 @ 18-28), read to include a morphology analysis system (col. 1 @ 46-52), a system to analyze the order and timing of atrial and ventricular events (col. 1 @ 52-58) and an interval variability system (col. 15 @ 27-57). Trending of a plurality of values can be using to control the therapy (col. 14 @ 24-41). The application of an atrial discrimination algorithm can be programmed by the physician to occur only after a maximum tracking rate has been established (col. 1 @ 59 – col. 2 @ 6; col. 14 @ 17-21; steps 11 and 12; col. 23 @ 11-19). Pacing is controlled by the microprocessor (col. 7 @ 29-67). Based on the effect of the pacing, the discrimination criteria can be altered (col. 26 @ 40 – col. 27 @ 58). Therapies are programmed into the device and more aggressive therapy can be scheduled based on the response to therapy or on the rate

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of tachycardia (col. 8 @ 51 – col. 9 @ 18). Three level of tachycardia can be distinguished as fast tachycardia, fibrillation or slow tachycardia (col. 14 @ 42-44).

As to discrimination criteria for distinguishing at least two different types of regular rapid supraventricular heart rates, fast atrial flutter and slower rate supraventricular tachycardia, where an indication corresponding to the type of heart rate is sent to the processor and the processor controls the atrial antitachycardia pacing of the heart according to the identified type of supraventricular tachycardia, the Gillberg et al. reference does disclose discrimination criteria for distinguishing at least two different types of regular rapid supraventricular heart rates (col. 19 @ 2-9; col. 20 @ 13-19), atrial flutter or fibrillation, read as fast atrial flutter tachycardia, (col. 20 @ 20 – col. 21 @ 7; col. 23 @ 3 – col. 25 @ 45) and sinus tachycardia or AV nodal re-entrant tachycardia, read as slower rate supraventricular tachycardia (col. 21 @ 8-54), where an indication corresponding to the type of heart rate is sent to the processor, and the processor controls the atrial antitachycardia pacing of the heart corresponding to the identified type of supraventricular tachycardia (col. 7 @ 4-67; col. 17 @ 39-61).

As to claims 1, 14, 30, 44 and 62, and pacing in a first manner and second manners for the supraventricular tachycardias/ atrial flutter and slower rate tachycardia, a unique therapy (figure 11 – 632, 634) is programmed in the microprocessor for each type of tachycardia (col. 3 @ 19-27; col. 7 @ 4-28; col. 8 @ 51-65; col. 14 @ 9-13; col. 17 @ 45-47; col. 26 @ 3-5). The regularity of the atrial rhythm, atrial flutter, is monitored to determine appropriate therapy (col. 23 @ 21-26).

As to claims 9, 10 and 39-41, and providing ventricular pacing, ventricular pacing is taught when atrial arrhythmias are detected (col. 18 @ 51-54; col. 19 @ 57-59;

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col. 20 @ 7-10).

As to claim 43 and trending output values, recirculating buffers collect values to control the pacer in response to the data trends (col. 7 @ 4-17).

The Applicant's arguments filed 4/14/03 have been fully considered but they are not convincing.

As to claims 1, 14, 30, 44 and 62, and pacing in a first manner and second manners for the supraventricular tachycardias/ atrial flutter and slower rate tachycardia, the Applicant appears to argue the AF is an irregular rate and a single type of AT therapy is provided, hence Gillberg et al. do not disclose the instant invention. The Examiner disagrees. Multiple unique therapies (figure 11 – 632, 634) are programmed in the microprocessor for each type of tachycardia (col. 3 @ 19-27; col. 7 @ 4-28; col. 8 @ 51-65; col. 14 @ 9-13; col. 17 @ 45-47; col. 26 @ 3-5). The regularity of the atrial rhythm, atrial flutter, is monitored to determine appropriate therapy (col. 23 @ 21-26).

As to claims 9, 10 and 39-41, and providing ventricular pacing, the Applicant appears to argue Gillberg et al. do not teach ventricular pacing in the presence of atrial arrhythmias. The Examiner disagrees. Gillberg et al. teach ventricular pacing when atrial arrhythmia is also detected (col. 18 @ 51-54; col. 19 @ 57-59; col. 20 @ 7-10).

As to claim 43 and trending output values, the Applicant asserts Gillberg et al. do not teach using collected values to control pacing. The Examiner disagrees. Gillberg et al. teach using recirculating buffers to collect values to control the pacer (col. 7 @ 4-17).

***Claim Rejections - 35 USC § 103***

4. Claims 4, 15, 34 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillberg et al. (US 5755736) in view of Ayers et al. (US 5549641). As discussed in paragraph 3 of this action, Gillberg et al. discloses the claimed invention except for distinguishing between fast atrial flutter at a first high rate and a second atrial flutter at a second lower rate.

Ayers et al. teaches atrial fibrillation therapy using identification between fast atrial flutter at a first high rate and a second atrial flutter at a second lower rate for the purpose of precisely identifying the arrhythmia so the therapy can be matched to the relative degree of organization/ disorganization of the detected atrial arrhythmia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used distinguishing between fast atrial flutter at a first high rate and a second atrial flutter at a second lower rate in the Gillberg et al. system in order to provide more targeted atrial arrhythmia therapy so normal sinus rhythm is quick reestablished, preventing the occurrence of a stroke, palpitations or dizziness (abstract; col. 1 @ 7-22; col. 6 @ 55-65).

***Statutory Basis***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703 605-4355). The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

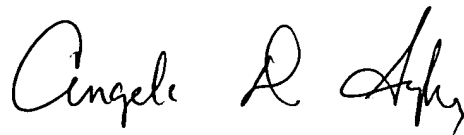
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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at telephone number (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

7/26/03



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